REMARKS

Applicants' invention relates to biocompatible matrices for the delivery of gases, such as oxygen, and other agents for the treatment of compromised tissues. Applicants respectfully request reconsideration of the present application in view the foregoing amendments and remarks. In order to facilitate prosecution, Claims 1, 5-6, and 12 have been amended and Claims 13-20 have been cancelled. New Claims 21-33 have been added. Support for claim amendments, and the new claims can be found throughout the specification. No new matter has been added by these amendments. After entry of the present amendments, Claims 1-12, and 21-33 will be pending. Claims 13-20 are withdrawn from consideration, and Applicants reserve the option of prosecuting these claims at a later time. The specification has been amended to include the chemical nomenclature for "TEMED." No new matter has been added.

Election/Restriction Requirement

In the office action dated December 18, 2001, the Examiner issued a restriction requirement directed to the following groups of claims:

I. Claims 1-12 and 14-20 drawn to a matrix, classified in class 424, subclass 443.

II. Claim 13 drawn to a method for treating compromised tissue, classified in 424, subclass 78.06.

The Examiner stated that the inventions are distinct because they are related as product and process of use. Applicants respectfully traverse.

As explained in Applicants' facsimile communication dated March 12, 2002, Claims 14-20 were intended to be directed to methods for treating compromised tissue. Due to a typographical error, Claims 14-20 contained the word "matrix" instead of the word "method". Applicant requested that an Examiner's Amendment be made in order to address

this discrepancy but this request was denied, and the restriction requirement as originally issued (directed to Group I (Claims 1-12 and 14-20) and Group II (Claim 13)), was maintained.

Applicants submit that the matrix of the present invention, and method of treating using the matrix, are so interrelated that searching the prior art for these inventions should not place a serious burden on the Examiner. Nevertheless, in order to facilitate prosecution, Applicants elect prosecution of the claims directed to the matrix as recited in Claims 1-12 and new Claims 21-33. Applicants have herein cancelled Claims 13-20, but reserve the option of prosecuting these claims at a later time.

Claim rejection under 35 U.S.C. § 102(b) and § 103(a)

The Examiner rejected Claims 1-20 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over, U. S. Patent No. 5,792,090 to Ladin (hereinafter *Ladin*).

The Examiner stated that *Ladin* relates to the healing of surface wounds by applying an oxygen generating wound dressing. The Examiner stated that the wound is covered [by a dressing having] an occlusive layer, which may be formed from hydrocolloids or gels, including guar gum and polyacrylamide. The Examiner also stated that hydrogels can be formed by the copolymerization and crosslinking of hydrophilic and hydrophobic monomers. In addition, the Examiner further explained that the *Ladin* wound dressing contains an oxygen permeable membrane, and an oxygen supply solution reservoir [adapted] to receive an aqueous liquid that preferably contains hydrogen peroxide. The Examiner added that *Ladin* teaches the treatment of surface wounds, such as burns, scalds and ulcers.

Applicants respectfully traverse these rejections for the following reasons. Unlike the *Ladin* wound dressing, the claims of the present invention are directed to a biocompatible matrix comprising a dispersion of both a non-gellable polysaccharide and oxygen, creating an oxygen-rich, **closed cell** polymer foam. The *Ladin* reference does not teach, or suggest an oxygen-rich closed cell polymer foam, containing a dispersion of a non-gellable

polysaccharide and a dispersion of oxygen. Therefore, Applicants respectfully submit that Claims 1-12 are not anticipated by, nor obvious over, *Ladin*, and request that this rejection be withdrawn.

A unique and desirable feature of the present invention is that it comprises a self-contained wound dressing that can be directly applied to a wound making it useful under any circumstances. In contrast, the *Ladin* device is not as versatile because the oxygen delivery mechanism requires a secondary reaction and additional input prior to oxygen delivery. The distinctive **closed cell** polymer foam of the present invention is virtually saturated in oxygen and **immediately** transports oxygen to the desired site via a concentration gradient; the user simply applies the dressing to the appropriate location. The *Ladin* device however is limited in its versatility primarily because it is comprised of several separate components, in particular an oxygen permeable membrane, an oxygen supply solution reservoir (adapted to receive an aqueous liquid capable for supplying oxygen through chemical reaction) and solid, immobilized catalyst. In addition, since an actual chemical reaction must take place in order to generate oxygen, actual delivery of oxygen is delayed and not immediate. The *Ladin* device is a multicomponent, multistep, cumbersome device, unlike the self-contained and efficient oxygen delivery matrix of the present invention. Furthermore as stated in the patent, the *Ladin* device comprises and **open cell** formation (see for example abstract line 12, column 5, line 59, column 12, line 63) as compared to the **closed cell** formation of the present invention.

More specifically, the present invention comprises an oxygen-rich, closed cell foam that can be manufactured from a polyacrylamide-guar gum matrix. The oxygen is generated by the catalytic conversion of hydrogen peroxide to gaseous oxygen. This reaction occurs during the manufacturing of the matrix, and results in the formation of "bubbles" of oxygen gas in the matrix. The end result is a "foam-like" appearance, or a closed cell (bubble) foam. When the dressing is placed in contact with moisture, i.e., a wound, the oxygen bubbles dissolve in the liquid and diffuse to the wound.

The *Ladin* device, on the other hand, does not teach or suggest closed cells rich in oxygen. This device is secured over a wound, and hydrogen peroxide is introduced into reservoir area where it contacts the catalyst. The decay of the hydrogen peroxide generates oxygen, which then permeates to the wound. The reservoir is located between a roof constructed of non-oxygen permeable material, and a floor constructed of an oxygen permeable material, and therefore, the generated oxygen permeates towards the oxygen permeable membrane and thus towards the wound.

In light of the foregoing and in summary therefore, the present invention is distinct and non-obvious over the *Ladin* device for the following reasons:

Applicants' Wound Dressing	*Ladin's* Wound Dressing
→self-contained unit, oxygen is captured in the dressing during manufacture and dressing is ready for immediate use	→multicomponent unit, generates oxygen after being placed on wound site, oxygen delivery is delayed and not immediate
→closed cell oxygen rich foam	→open cell formation lacking oxygen
→homogenous polymer	→multicomponent unit

CONCLUSION

The foregoing is a complete response to the Office Action dated December 18, 2001. Applicants respectfully submit that Claims 1-12, and 21-33 are patentable. Early and favorable consideration is solicited.

No fees are believed due; however, the Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If Examiner believes there are other issues that can be resolved by a telephone interview, or that there are any informalities that remain in the application which may be corrected by the Examiner's amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,

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Version to Show Changes Made

In the Specification

Pursuant to 37 C.F.R. §1.21(b)(1)(iii), the following replacement paragraphs of the specification show all changes made by the foregoing amendment relative to the previous version of these paragraphs. Omitted text is in brackets. New text is underlined.

The following paragraph beginning on page 20, line 8, and ending at line 23, has been amended as follows:

A preferred embodiment of the present invention comprises a suspension of components for the formation of a polymer, such as acrylamide, together with various solvents such as lipids, water and alcohol. More particularly, a preferred composition comprises a water suspension containing acrylamide, bis acrylamide, glycerol, guar gum and isopropyl alcohol. The suspension is mixed to completely hydrate the guar gum and dissolve the other ingredients. Subsequently, a solution such as a TEMED (N,N,N',N'-tetramethylethylene diamine) solution is sequentially added together with ammonium persulfate and sodium carbonate. The material is then mixed and poured into molds and allowed to gel. The gelled sheets are transferred into a drying oven for dehydration and are then rehydrated with a solution of hydrogen peroxide. After a 'rest period' of several hours, the foamed oxygen-containing material may then be cut to size and sterilized, for example, by electron beam irradiation.

In the Claims

Pursuant to 37 C.F.R. §1.121(c)(1)(ii), a version of the rewritten claims, marked up to show all the changes relative to the previous version of the claims, is now set forth with deleted text shown in [brackets] and added text shown in underlining:

1. (Once amended) An oxygen-delivery matrix, comprising, [a biocompatible matrix comprising a polymer network and a non-gellable polysaccharide, and oxygen]

a biocompatible matrix,

wherein the biocompatible matrix comprises a polymer network, a non-gellable polysaccharide, and oxygen,

and wherein the non-gellable polysaccharide and oxygen are dispensed throughout the polymer network, creating an oxygen-rich, closed cell polymer foam.

5. (Once amended) The matrix of Claim 1, wherein the oxygen is [provided by the formation of a closed cell foam] formed by [the] an [in situ] *in situ* production of oxygen.

6. (Once amended) The matrix of Claim 5, wherein the [in situ] *in situ* production of oxygen results from the decomposition of a peroxide [such as hydrogen peroxide].

12. (Once amended) The matrix of Claim 1, wherein the [biocompatible] polymer [is] comprises a natural or synthetic polymer.